

EXHIBIT G



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October 8, 2018

VIA E-MAIL

Special Master David Cohen
U.S. District Court for the
Northern District of Ohio
Carl B. Stokes U.S. Courthouse
801 West Superior Avenue
Cleveland, Ohio 44113

**RE: In Re National Prescription Opiate Litigation
U.S. District Court for the Northern District of Ohio
Case No. 1:17-md-2804**

Dear Special Master Cohen:

We write to address an issue concerning certain Defendants' improper narrowing of their discovery responses to exclude relevant information. Specifically, these Defendants refuse to provide what they call "dispensing" information on the grounds that the only basis for their liability in this case concerns their role as distributors, and thus, they erroneously contend that the dispensing data is not relevant to Plaintiffs' claims. We ask that you issue a ruling compelling Defendants to: (1) produce documents concerning their dispensing practices, policies, and procedures, including documents reflecting any dispensing violations, as requested in Plaintiffs' document requests; and (2) produce documents pursuant to Paragraph 9(k)(ii) of Case Management Order No. 1 concerning their alleged violations of dispensing laws and regulations.

As explained in detail below, documents concerning dispensing practices are highly relevant to Defendants' liability as distributors. In the course of distributing controlled substances to pharmacies, Defendants are required to conduct "know your customer" due diligence, which includes, among other things, an evaluation of each pharmacy's dispensing practices. According to the DEA, this includes knowing who the top prescribers are, knowing the volumes of prescriptions written, the types of prescriptions written, and other dispensing information that may bear on potential diversion. In the case of the Pharmacy Defendants, because of the vertically integrated nature of their operations, where they both distribute and dispense controlled substances, they possess detailed "know your customer" information about each store's dispensing practices. All of this information is relevant to Plaintiffs' claims.



To illustrate this point, consider the issue of recordkeeping at a pharmacy, which certain Defendants claim is demonstrably irrelevant dispensing information. Pharmacies must keep detailed accounting records concerning controlled substances to account for each and every pill that travels through the store. If such records are not maintained, there is no way of knowing whether a depleted inventory is the result of theft and diversion, or if the pills were dispensed to legitimate patients with a valid prescription. Indeed, contrary to Defendants' position, in announcing a CVS settlement for such violations,¹ the United States Attorney's Office issued a press release containing the following statement: "The nation is in the midst of an opioid crisis and all entities that distribute controlled substances must hold the frontline. **Regulatory compliance and accurate recordkeeping are key in a pharmacy's ability to prevent prescription drug diversion.**"² If a Pharmacy Defendant does not consider such information in connection with distributing pills to its stores, how does it know that the order is not being requested to replace inventory lost to diversion, thereby contributing to the epidemic, or if the order is made to fill a legitimate demand?

In 2009, the Department of Justice announced a settlement with Rite Aid which concerned "a pattern of violations of the CSA, including . . . knowingly fill[ing] prescriptions for controlled substances that were not issued for a legitimate medical purpose pursuant to a valid physician-patient relationship . . . fail[ing] to notify the DEA in a timely manner of significant thefts and losses of controlled substances, thus permitting the diversion of controlled substances to continue and undermining DEA's ability to investigate such thefts and/or losses . . . [and] fail[ing] to properly execute DEA forms used to ensure that the amount of Schedule II drugs ordered by Rite Aid were actually received."³ Counsel has attempted to meet and confer regarding dispensing data, but Rite Aid has thus far refused to produce such information in discovery. Instead, Rite Aid generally limits all of its responses to *exclude* information relating to its "dispensing" of opioids. Moreover, **Rite Aid refuses to produce information concerning this DEA settlement, as required under Paragraph 9(k)(ii) CMO No. 1**, because Rite Aid believes it concerns a dispensing violation, rather than a distribution violation. We raised this on our calls with them many times, but Rite Aid has not relinquished its position.

Defendants cannot reasonably dispute that these documents are relevant. Walgreens recently amended its Interrogatory responses to aver that "Walgreens uses, and previously used, data from its own pharmacies to evaluate orders of Opioids from those pharmacies." *See*

¹ "CVS pharmacies failed to provide effective controls and procedures to guard against diversion when CVS failed to: record the amount received and the date received of Schedule II drugs on DEA-222 Forms; maintain DEA-222 Forms and keep them separate from other records; record the date of acquisition of controlled substances in Schedules II through V; maintain invoices for drugs in Schedules III through V and keep the records separate from non-controlled substance records; and conduct a biennial inventory on one specific day." <https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act>.

² *Id.* (emphasis added).

³ <https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations>.



Walgreens's Amended Response to Interrogatory No. 6. Similarly, CVS's internal policy for ensuring compliance with the DEA's Controlled Substance Suspicious Order Monitoring regulation includes a review of "all pharmacy orders for Controlled Substances."⁴ CVS's procedure for ensuring compliance includes three phases: Identify, Review, and Action. CVS assigns responsibility for each phase to individuals who are members of both the distribution and dispensing/pharmacy teams, among others.⁵ That same document then identifies an example of SOM that would implicate CVS's dispensing activities:

For suspicious Orders, the SOM team will create milestone(s) requiring action from the applicable business unit(s) responsible for creating and implementing remediation plans.

- Example – **The SOM team has blocked a store order due to an issue regarding pharmacy dispensing.** The SOM team would create a milestone for **Pharmacy Operations (and any other applicable business units)** advising them that an action plan needs to be completed to resolve the identified **dispensing issue**. . . .

In a subsequent letter to the DEA, CVS boasted that part of the reason it had so few suspicious orders was that "there are additional due diligence processes in [its] pharmacy operations group which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores."⁶ By its own admission, CVS's ability to monitor its own dispensing practices is a primary part of its "strategy on how [it] manage[s] suspicious orders."⁷

Documents produced by AmerisourceBergen ("ABDC") confirm the direct connection between "dispensing" activities at the pharmacy and the duty to control diversion as a distributor. For example, an ABDC PowerPoint presentation defines "drug diversion" as "any act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient." Notably, it does not limit diversion as occurring between the manufacturer and the pharmacy. In fact, ABDC explicitly states that "drug diversion" can include "the outright theft of the drugs, or it can take the form of a variety of deceptions such as doctor shopping, forged prescriptions, or dispensing drugs for other than a legitimate medical purpose."⁸ The "red flags of diversion" identified in that PowerPoint include "dispensing large quantities of Oxycodone prescriptions . . . when compared with total number of prescriptions," and "dispensing a high percentage of Oxycodone 30 mg prescriptions versus all other Oxycodone strengths being dispensed."⁹

⁴ See CVS-MDLt1-000000001.

⁵ See CVS-MDLt1-000000001 at 02.

⁶ CVS-MDLT1-0003517-3518.

⁷ See CVS MDLT1-0000409.

⁸ ABDCMDL00269475, at 2.

⁹ ABDCMDL00269475, at 13-14.



Special Master David Cohen
October 8, 2018
Page 4

The same is true for other Defendants. Documents produced by Walgreens reveal that they utilize dispensing data as a component of their suspicious order monitoring program.¹⁰ Documents produced by Walmart illustrate that “contact” with pharmacists is a critical factor in its investigation of orders identified as suspicious.¹¹ These documents also confirm that information from “the store” must be gathered when investigating a “SOM incident.” While just a few examples, this evidence makes clear that SOM implicates more than just the distribution business units of these Defendants. It also shows that they rely on dispensing data to monitor diversion.

Because dispensing practices constitute a substantial part of many of the Distributor Defendants’ suspicious order monitoring programs, they too should be required to produce responsive documents and other evidence relating to the dispensing portion of their supply chain activities. Accordingly, Plaintiffs respectfully request that this Court enter an order requiring that these Defendants provide updated discovery responses by a date certain that are not limited to their “role as a distributor,” but reflect their many relevant roles and activities within the broader supply chain.

As you may recall, we briefly raised this issue in our August 31, 2018 letter, but a ruling was never issued in response. Because Defendants continue to withhold this evidence, we are now writing to formally renew our request that Defendants be required to produce responsive documents concerning “dispensing,” regardless of whether it is specifically tied to their role as distributors.

Best regards,

/s/ Mark Pifko

Mark Pifko

cc: Defendants’ Counsel (xALLDEFENDANTS-MDL2804-Service@arnoldporter.com)
Plaintiffs’ Counsel (MDL2804discovery@motleyrice.com)

¹⁰ See WAGFLDEA00001518 (noting Walgreens “[m]onitor[s] and flag[s] if we dispense outside of the “normal” range” for controlled substances it supplies to itself, and Cardinal Health monitors and flags for controlled substances it supplies to Walgreens).

¹¹ See WAGFLDEA00000846 (noting a Walgreens CII Function Manager was contacting a pharmacy supervisor regarding unusual levels of sales and orders of prescription opioids).